Michael R. Griffinger (MG-2944)
Michael Quinn (MQ-2722)
GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE, PC
One Riverfront Plaza
Newark, New Jersey 07102
Ph: 973-596-4500

Attorneys for Defendant Amgen Inc. and Amgen USA Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ORTHO BIOTECH PRODUCTS, LP.,	:	
Plaintiff	:	**Civil Action No.: 05-cv-4850-SRC-JJH**
-v-	:	
	:	**ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS AMGEN INC., and AMGEN USA INC.**
AMGEN INC., and AMGEN USA INC.,	:	
Defendants.	:	

ANSWER

Defendants Amgen Inc., and Amgen USA Inc., (collectively, "Amgen") answer the Compliant of plaintiff Ortho Biotech Products, L.P. ("plaintiff" or "Ortho"), upon knowledge with respect to their own acts, and upon information and belief as to all other matters, as follows:

PRELIMINARY STATEMENT

This is not an antitrust case. It is merely the latest effort by Ortho to deter or limit Amgen's ability to compete with Ortho in providing Red Blood Cell Growth Factor ("RBCGF") drugs to patients, physicians, and other providers for use in the treatment of anemia in patients who are not on dialysis. Ortho's prior litigation efforts to this end have failed, as should this one.

Since Amgen first began marketing Aranesp® for chemotherapy-induced anemia in late 2001, consumer welfare among RBCGF users has been enhanced remarkably: prices have fallen, availability has been heightened, treatment has increased, and competition in all respects has flourished. Ortho's attack on Amgen's discount program is simply a transparent attempt to undermine, rather than promote, competition for RBCGF drugs.

Indeed, Ortho, individually and with the Johnson & Johnson family of companies with which it is affiliated, is a savvy and aggressive competitor, no stranger to bundled discounts of its own. In large measure due to the actions of Ortho and other Johnson & Johnson affiliates, bundled discounts are prevalent and well-accepted among purchasers of pharmaceutical and biotech drug products. Further, Ortho is fully capable of responding to Amgen's discount program with an array of appropriate competitive activities, and there is simply no chance – none

– that Ortho will abandon the sale of Procrit, believed to be one of the most profitable products in the broad portfolio of the Johnson & Johnson group of companies.

Accordingly, Amgen respectfully urges this Court to deny Ortho's request for a preliminary injunction, a permanent injunction, and damages, and to enter judgment forthwith for Amgen.

Complaint:

1. This antitrust action, brought under Sections 1 and 2 of the Sherman Act, involves an anti-competitive tying arrangement and pricing scheme implemented by defendant Amgen in the oncology clinic market. The scheme ties substantial purchases of Amgen's Red Blood Cell Growth Factor ("RBCGF") drug to its dominant White Blood Cell Growth Factor ("WBCGF") drugs. Both WBCGF and RBCGF drugs are needed by oncology clinics to treat cancer patients. The purpose of Amgen's scheme is to monopolize the market for sales of RBCGF drugs to oncology clinics. The result will be less competition, less physician and patient choice and an increased expense to the public health system.

Answer:

1. Amgen admits that Plaintiff purports to bring its claims under Sections 1 and 2 of the Sherman Act. Amgen admits that RBCGF and WBCGF are among the drugs that may be used by a provider of health care services for the treatment of cancer patients and patients receiving chemotherapy. They are administered in oncology clinics and other settings in varying proportions depending on the patient's needs. Amgen denies that the challenged conduct is a tying arrangement, or that it is anticompetitive. Amgen denies Plaintiff's claim that the oncology clinic market is a properly defined relevant antitrust market. Amgen denies that it has committed any violations of the Sherman Act or that Plaintiff is entitled to any relief whatsoever. Amgen denies each and every remaining allegation contained in Paragraph 1 of the Complaint.

Complaint:

2. Ortho sells Procrit®. Amgen sells Aranesp®. Both are RBCGF drugs that compete head-to-head in a two-player market. Annual combined sales to oncology clinics of these two products are projected to exceed $2.8 billion in 2005.

Answer:

2. Amgen admits that Ortho sells Procrit®. Amgen admits that it sells Aranesp®, and that both Procrit® and Aranesp® are RBCGF drugs. Amgen admits that Aranesp® has a unique molecular structure that is different from Procrit® and provides certain clinical options for physicians treating anemia. Amgen admits that annual combined sales to oncology clinics of Procrit® and Aranesp® have been projected to exceed $2.8 billion in 2005. Amgen denies each and every remaining allegation contained in Paragraph 2 of the Complaint.

Complaint:

3. Amgen also sells Neulasta® and Neupogen®, which are WBCGF drugs with a combined 98% market share of sales to oncology clinics. Amgen has a monopoly in the market for WBCGF drugs. Ortho does not sell a WBCGF drug.

Answer:

3. Amgen admits that it sells the WBCGF drugs Neulasta® and NEUPOGEN®. Amgen admits that currently Ortho does not sell a WBCGF drug but upon information and belief alleges that there are several other companies engaged in the development of WBCGF drugs and products to compete with WBCGF drugs. Amgen denies that WBCGF drugs constitute a properly defined antitrust market. Amgen denies each and every remaining allegation contained in Paragraph 3 of the Complaint.

Complaint:

4. Aranesp now accounts for roughly 66% of RBCGF drug sales to oncology clinics. Aranesp's share has increased by 46% over the past 18 months as the result of Amgen's illegal pricing practices that penalize oncology clinics on purchases of its monopoly WBCGF drugs, when those clinics do not agree to purchase significant volumes of its Aranesp, instead of Procrit.

Answer:

4. Amgen denies each and every allegation contained in Paragraph 4 of the Complaint.

Complaint:

5. On October 1, 2005, Amgen's pricing scheme became considerably more coercive. Amgen has now imposed even steeper pricing penalties on Amgen's monopoly WBCGF drugs when oncology clinics do not purchase up to 75% of their RBCGF drugs from Amgen. In fact, if a clinic wishes to continue to receive the same level of rebates it had been receiving under the pre-October 1, 2005 contract, the clinic must increase its Aranesp share up to 90%.

Answer:

5. Amgen denies each and every allegation contained in Paragraph 5 of the Complaint.

Complaint:

6. Amgen's pricing scheme has reached the point where, for a substantial percentage of its patients, an oncology clinic is put in a completely untenable position. A clinic will end up losing several hundred dollars per administration of Amgen's leading WBCGF drug because the cost of buying the drug (absent the contractual rebates) vastly exceeds the amount of government reimbursement. The clinic can only gain access to the rebates on Amgen's monopoly WBCGF drugs when they purchase virtually all of their RBCGF drug requirements from Amgen.

Answer:

6. Amgen denies each and every allegation contained in Paragraph 6 of the Complaint.

Complaint:

7. Defendant's conduct constitutes a tying arrangement in violation of Section 1 of the Sherman Act under either a *per se* or Rule of Reason analysis. As the result of Amgen's monopoly power in the sale of WBCGF drugs to oncology clinics, Amgen's pricing scheme leaves oncology clinics with no economic alternative but to purchase virtually all RBCGF drugs from Amgen. Moreover, WBCGF and RBCGF drugs are distinct and separate products and a not insubstantial amount of commerce is involved.

Answer:

7. Amgen admits that WBCGF and RBCGF drugs are distinct and separate products and are sold separately. Amgen denies each and every remaining allegation contained in Paragraph 7 of the Complaint.

Complaint:

8. Amgen's actions also violate Section 2 of the Sherman Act. The purpose of Amgen's anticompetitive pricing scheme is to monopolize the oncology clinic market for RBCGF drugs in the United States in which Procrit is Amgen's only competitor. There is a dangerous probability that, by engaging in this exclusionary conduct, Amgen will succeed in its monopolistic plans.

Answer:

8. Amgen denies each and every allegation contained in Paragraph 8 of the Complaint.

Complaint:

9. The anticompetitive conduct at issue here will irreparably harm Ortho and is not in the public interest. If Amgen is not blocked from pursuing this new pricing scheme, Procrit's ability to compete in the oncology clinic market for RBCGF drugs largely will cease. Since Procrit was introduced in 1991, it has been used to treat millions of patients who suffer from chemotherapy-induced anemia ("chemo-induced anemia"). Procrit was the first RBCGF drug on the market and it improved the lives of millions of patients. Ortho is viewed by thought leaders in the oncology market as one of the pioneers in addressing the needs of cancer patients undergoing chemotherapy. As a result, Ortho has longstanding relationships with oncology clinics and has built-up enormous goodwill in the Procrit brand.

Answer:

9. Amgen admits that Procrit® was introduced in 1991. Amgen admits that RBCGF drugs, including Procrit®, have improved the lives of many patients, but lacks information and knowledge sufficient to form a belief as to the truth of the allegation that millions of patients with chemotherapy-induced anemia ("chemo-induced anemia") have been treated with Procrit® and, on that basis, denies this allegation. Amgen lacks information or knowledge sufficient to form a belief concerning the nature or extent of Ortho's relationships with purchasers of Procrit®, and the identities and views of so-called "thought leaders" referred to, and accordingly denies those allegations. Amgen denies each and every remaining allegation contained in Paragraph 9 of the Complaint.

Complaint:

10. Moreover, denying clinics and ultimately patients' access to Procrit is not in the public interest and will harm consumers. Physicians should not face economic coercion. Forcing physicians who treat cancer patients to abandon Procrit as the only economically viable way to gain access to another badly needed drug for their patients, is not, by any measure, in the public interest.

Answer:

10. Amgen avers that Paragraph 10 asserts arguments, not facts, and thus, on that basis, Amgen denies each and every allegation contained in Paragraph 10 of the Complaint.

Complaint:

11. For these reasons and to remedy the injuries that will be caused and have been caused by Amgen's anticompetitive conduct, Ortho seeks a preliminary and permanent injunction as well as treble damages.

Answer:

11. Amgen admits that Plaintiff purports to seek a preliminary and permanent injunction as well as treble damages, but denies each and every remaining allegation contained in Paragraph 11, and further denies that Plaintiff is entitled to any relief whatsoever.

JURISDICTION AND VENUE

Complaint:

12. This complaint is filed under Section 16 of the Clayton Act, 15 U.S.C. § 26, to prevent and restrain violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. § 1 and 2, and for damages under Section 4 of the Clayton Act, 15 U.S.C. § 15. This Court has jurisdiction over the federal antitrust law claims alleged herein under 28 U.S.C. §§ 1331, 1337, 2201 and 2202.

Answer:

12. Amgen admits that Plaintiff purports to bring its claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, Sections 1 and 2 of the Sherman Act, 15 U.S.C. § 1 and 2, and for damages under Section 4 of the Clayton Act, 15 U.S.C. § 15. Amgen admits that the Plaintiff's allegations, though denied, create jurisdiction over the federal antitrust law claims alleged herein under 28 U.S.C. §§ 1331, 1337, 2201 and 2202. Amgen denies each and every remaining

allegation in Paragraph 12, and further denies that it has committed any violation of law or that Plaintiff is entitled to any relief whatsoever.

Complaint:

13. Defendant transacts business and is found in this district. Substantial interstate trade and commerce involved and affected by the alleged violations of antitrust law occurs within this district. The acts complained of have had, and will have, substantial anticompetitive effects in this district. Venue is proper in this district under 28 U.S.C. § 1391 and 15 U.S.C. §§ 15, 22 and 26, particularly as plaintiff Ortho resides here.

Answer:

13. Amgen admits that it transacts business and is found in this district. Amgen admits that Plaintiff's allegations, though denied, are sufficient to vest subject matter jurisdiction and venue in the court. Amgen denies each and every remaining allegation contained in Paragraph 13 of the Complaint.

THE PARTIES

Complaint:

14. Plaintiff Ortho is a limited partnership organized and existing under the laws of New Jersey with its principal place of business located in Bridgewater, New Jersey, Ortho is one of the Johnson & Johnson family of companies. Johnson & Johnson is a corporation with its principal place of business in New Brunswick, New Jersey. Ortho sells Procrit, the drug that is the target of Amgen's monopolistic schemes.

Answer:

14. Upon information and belief, Amgen admits that Ortho is a limited partnership organized and existing under the laws of New Jersey with its principal place of business located in Bridgewater, New Jersey. Upon information and belief, Amgen admits that Ortho is one of the Johnson & Johnson family of companies. Upon information and belief, Amgen admits that

Johnson & Johnson is a corporation with its principal place of business in New Brunswick, New Jersey. Amgen admits that Ortho sells Procrit®. Amgen denies each and every remaining allegation in Paragraph 14 of the Complaint.

Complaint:

15. Defendant Amgen is a corporation organized and existing under the laws of Delaware with its principal place of business in Thousand Oaks, California. Amgen, among other things, manufactures and sells Aranesp as well as two WBCGF drugs, Neupogen and Neulasta.

Answer:

15. Amgen Inc., admits that it is a corporation organized and existing under the laws of Delaware with its principal place of business in Thousand Oaks, California and with a subsidiary it manufactures NEUPOGEN®, Neulasta® and Aranesp®. Amgen USA Inc., admits that it is a corporation organized and existing under the laws of Delaware with its principal place of business in Thousand Oaks, California and that sells NEUPOGEN®, Neulasta® and Aranesp®

Complaint:

16. Severe anemia is most commonly seen in patients (1) with chronic kidney disease either pre-dialysis or while undergoing dialysis, (2) undergoing chemotherapy or (3) undergoing zidovudine treatment for HIV disease. Anemia is caused by the depletion of the human hormone erythropoietin, which is produced primarily by the kidneys and stimulates red blood cell production and maturation in the bone marrow. Chemotherapy, for example, depresses erythropoietin production, often leading to anemia. Many patients suffering from anemia cannot lead normal, productive lives.

Answer:

16. Amgen admits that severe anemia is most commonly seen in patients (1) with chronic kidney disease either pre-dialysis or while undergoing dialysis, (2) undergoing

chemotherapy or (3) undergoing zidovudine treatment for HIV disease, and that many patients suffering from anemia cannot lead normal, productive lives. Amgen denies each and every remaining allegation in Paragraph 16 of the Complaint.

Complaint:

17. Epoetin alfa is a synthetic form of erythropoietin that stimulates the production of red blood cells and is often referred to as a RBCGF drug. Prior to the introduction of epoetin alfa drugs, the treatment for more severe cases of anemia was whole blood or red blood cell transfusions.

Answer:

17. Amgen admits that prior to the introduction of epoetin alfa drugs, the treatment for more severe cases of anemia was whole blood or red blood cell transfusions. Amgen denies each and every remaining allegation in Paragraph 17 of the Complaint.

Complaint:

18. Ortho sells Procrit®, a branded version of epoetin alfa. By Product License Agreement ("PLA") executed as of September 30, 1985, Amgen granted Ortho an exclusive license under Amgen's patents to market and sell epoetin alfa in the United States for anemia in humans resulting from all treatments except anemia in patients undergoing dialysis for end stage renal disease ("ESRD"). Under the PLA, Amgen retained the right to market an epoetin alfa product for humans in this one field, which it does under the brand name Epogen.

Answer:

18. Amgen admits that Ortho sells Procrit®, a branded version of Epoetin alfa. Amgen admits that under the Product License Agreement ("PLA") executed as of September 30, 1985, Amgen Inc., granted Ortho a limited license to market and sell Epoetin alfa in the United States for all indications including anemia for human use, except use in the dialysis and diagnostics settings. Amgen admits that under the PLA, Amgen retained the right to market the Epoetin alfa molecule covered by the PLA for dialysis and diagnostics, which it does under the

brand name Epogen®. Amgen denies each and every remaining allegation contained in Paragraph 18 of the Complaint.

Complaint:

19. At the time of the PLA, the use of epoetin alfa to combat dialysis-induced anemia offered the greatest possibility for commercial success. However, there was no firm basis for predicting the viability of using epoetin alfa to treat anemia resulting from other disease states. Through costly research and clinical trials, Ortho demonstrated the efficacy of epoetin alfa to treat and reduce the need for transfusions in patients undergoing treatment for other diseases. Based upon this work, Ortho secured FDA approvals, beginning in 1991, to market Procrit for the treatment of persons who develop anemia as a consequence of (1) chemotherapy for cancer, (2) treatment of HIV infection with the pharmaceutical zidovudine, (3) chronic kidney diseases in pre-dialysis patients, and (4) in anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery.

Answer:

19. Upon information and belief, Amgen admits that, with the assistance of Amgen, Ortho submitted safety and efficacy data regarding Epoetin alfa which resulted in FDA approvals, beginning in 1991, to promote Procrit® for the treatment of persons who develop anemia as a consequence of (1) chemotherapy for cancer, (2) treatment of HIV infection with the pharmaceutical zidovudine, (3) chronic kidney diseases in pre-dialysis patients, and (4) in anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery. Amgen lacks information and knowledge sufficient to form a belief as to the truth of the remaining allegations and, on that basis, denies each and every remaining allegation contained in Paragraph 19 of the Complaint.

Complaint:

20. Since Procrit was launched in 1991, it has been prescribed to millions who suffer from anemia included in the four indications listed above and became the standard of care for the treatment of chemo-induced anemia. As a result of Procrit's success, Ortho has paid Amgen over $1.5 billion in royalties on Procrit sales.

Answer:

20. Amgen admits that since Procrit® was launched in 1991, it has been prescribed to many who suffer from anemia included in the four indications listed above and became for a period of time the standard of care for the treatment of chemo-induced anemia. Amgen admits that Ortho has paid Amgen over $1.5 billion in royalties on Procrit® sales. Amgen denies each and every remaining allegation of Paragraph 20 of the complaint.

Complaint:

21. Amgen decided to circumvent the market exclusivity it had granted to Ortho to sell epoetin alfa for all purposes other than dialysis. The result was Amgen's introduction of Aranesp, a synthetic form of erythropoietin known as darbepoetin alfa. It was formulated by modifying the epoetin alfa molecule, thereby circumventing the exclusive rights granted to Ortho on epoetin alfa. In 2002, Amgen received regulatory approval to sell Aranesp, a branded RBCGF drug, to treat chemo-induced anemia.

Answer:

21. Amgen admits that it manufactures and sells Aranesp®, which is a unique molecule and different from the Epoetin alfa molecule that Ortho is licensed to market as Procrit.® Aranesp® has an amino acid sequence that differs from the amino acid sequence of human erythropoietin and thus differs from the amino acid sequence of Procrit®. Amgen denies that Aranesp® is a synthetic form of erythropoietin. Amgen denies that Aranesp® was formulated by modifying the Epoetin alfa molecule. Amgen denies that the introduction of Aranesp® was, in any way, an effort to circumvent Ortho's rights under the PLA. To the contrary, when Ortho sought to obtain the rights to Aranesp® a three member arbitration panel ruled that the PLA did not impact or restrict Amgen's right to market and sell Aranesp® for the treatment of any condition. Ortho is not entitled to Aranesp® under the PLA. Amgen admits that in 2002 it received regulatory approval to sell Aranesp®, which also is a RBCGF drug, to treat chemo-induced anemia. The introduction of Aranesp®, offered for the first time a choice of

RBCGF products for use in the treatment of non-dialysis patients. Amgen denies each and every remaining allegation contained in Paragraph 21 of the Complaint.

Complaint:

22. Ortho's work and investment in Procrit, which demonstrated that RBCGF drugs could be safely, effectively and widely used to combat chemo-induced anemia, helped Amgen to secure FDA approval of Aranesp and to sell Aranesp into markets in which physicians had been educated by Ortho about the benefits of RBCGF drugs.

Answer:

22. Amgen denies each and every allegation contained in Paragraph 22 of the Complaint.

Complaint:

23. Given the scope of Amgen's patents, Ortho and Amgen are the only two competitors for the sale of RBCGF drugs to treat chemo-induced anemia in the United States. Gross sales to oncology clinics for Procrit and Aranesp are projected to exceed $2.8 billion in 2005.

Answer:

23. Amgen admits that Ortho and Amgen currently are the only suppliers of RBCGF drugs to treat chemo-induced anemia in the United States but avers on the basis of information and belief that other companies currently are developing RBCGF drugs and products to compete with RBCGF drugs. Amgen admits that gross sales of RBCGF drugs to United States oncology clinics for Procrit® and Aranesp® are projected to exceed $2.8 billion in 2005. Amgen denies each and every remaining allegation contained in Paragraph 23 of the Complaint.

Complaint:

24. Many cancer patients undergoing chemotherapy may, for different reasons, also require a WBCGF drug to combat neutropenia, a white blood cell deficiency that is potentially

life threatening. Neutropenia is a side effect of chemotherapy which potentially compromises a patient's immune system. The disease occurs not only in many patients undergoing chemotherapy, but in individuals suffering from a number of other diseases.

Answer:

24. Amgen admits the allegations contained in Paragraph 24 of the Complaint subject to the statement that neutropenia is a condition, not a disease.

Complaint:

25. Ortho does not sell a WBCGF drug, but Amgen does. Amgen sells two WBCGF drugs, Neupogen® and Neulasta®. The only other WBCGF drug sold is Leukine®, which is distributed by Berlex Laboratories.

Answer:

25. Amgen admits that currently Ortho does not sell a WBCGF drug and that Amgen sells two WBCGF drugs, Neupogen® and Neulasta®. Amgen admits that currently the only other WBCGF drug sold is Leukine®, which is distributed by Berlex Laboratories. On information and belief, Amgen states that other companies are engaged in the development of WBCGF drugs and products to compete with WBCGF drugs. Amgen denies each and every remaining obligation in Paragraph 25 of the Complaint.

Complaint:

26. Neupogen was Amgen's initial WBCGF drug. In 2002, Amgen introduced Neulasta, a WBCGF product, which has been modified so that one injection of Neulasta is roughly equal to 7 injections of Neupogen.

Answer:

26. Amgen admits that NEUPOGEN® was Amgen's first commercial WBCGF drug. Amgen admits that in 2002, Amgen introduced Neulasta®, a WBCGF product. Amgen lacks

information or knowledge sufficient to form a belief as to the truth of the allegation that Leukine must be administered intravenously, and, on that basis denied the allegation. Amgen denies each and every remaining allegation contained in Paragraph 26 of the Complaint.

Complaint:

27. Amgen dominates the sales of WBCGF drugs which have become the recognized standard of care for the treatment of neutropenia. Amgen has a 98% share of the sales to oncology clinics (with Neulasta alone having an 86% market share). Although Berlex's Leukine product has been on the market for many years, it has only a *de minimus* share of WBCGF sales. Unlike Amgen's WBCGF drugs which are administered by subcutaneous injection, Leukine must be administered intravenously - a longer and more costly process.

Answer:

27. Amgen admits that WBCGF drugs have become the recognized standard of care for the treatment of neutropenia for patients who do not require a transfusion. Amgen denies each and every remaining allegation contained in Paragraph 27 of the Complaint.

Complaint:

28. Virtually all oncology clinics administer both RBCGF and WBCGF drugs to patients. Given this fact and Amgen's monopoly on WBCGF drugs, these clinics must buy WBCGF drugs, particularly Neulasta, from Amgen.

Answer:

28. Amgen admits that most providers of cancer treatment, including oncology clinics, administer both RBCGF and WBCGF drugs to patients, but avers that the proportion of RBCGF drugs used to the WBCGF drugs used varies widely from clinic to clinic and time period to time period, and, further avers that the treatment regimen differs based on the type of cancer. Amgen admits that many clinics engaged in the treatment of cancer patients buy WBCGF drugs

from Amgen. Amgen denies each and every remaining allegation contained in Paragraph 28 of the Complaint.

Complaint:

29. This fact was not lost on Amgen as it developed a marketing plan for Aranesp. Almost from the outset, Amgen's strategy for selling Aranesp has been to penalize a clinic on the pricing of its dominant WBCGF drugs if the clinic did not purchase substantial amounts of Aranesp, a product that has competition. The volume requirements in Amgen's pricing schemes for its RBCGF and WBCGF drugs are, in fact, disguised market share requirements designed to reduce Procrit's share of clinic sales by means other than competition on the price of RBCGF drugs or their relative merits.

Answer:

29. Amgen denies each and every allegation contained in Paragraph 29 of the Complaint.

Complaint:

30. Amgen's penalties became even more coercive in the spring of 2004. At that time, Amgen began offering substantial "rebates" to oncology clinics on the condition that these facilities reach combined volume requirements for Amgen's RBCGF and WBCGF drugs. Amgen refers to these offerings on its RBCGF and WBCGF drugs as the Amgen Portfolio Contract ("APC").

Answer:

30. Amgen admits that during the spring of 2004 it offered discounts on its RBCGF and WBCGF drugs to providers and purchasers under the Amgen Portfolio Contract ("APC"), and that numerous providers and purchasers availed themselves of those discounts. Amgen states that the best evidence of the contents of its APC contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 30 of the Complaint.

Complaint:

31. Amgen's pricing to oncology clinics under its APC is broken into three groups - large, medium and small accounts - based on the amount of RBCGF and WBCGF drugs purchased. Each account is given dollar volume usage targets that once reached allows the clinic to earn a specified level of rebate. The dollar volume targets Amgen puts in each clinic's APC represent a specific percentage requirement of market share based on a clinic's historical usage. Rebates are earned when Amgen's share of the clinic's estimated total APC purchases reach those levels.

Answer:

31. Amgen states that the best evidence of the contents of its APC contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 31 of the Complaint.

Complaint:

32. For example, under the APCs in effect in the first half of 2004, a large account oncology clinic which purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen received a 13.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen received significantly greater rebates - a 25% rebate on its Aranesp purchases and a 25% rebate on its Amgen WBCGF drug purchases. An oncology clinic that did not meet its APCs volume requirements would only receive a minimal rebate or discount. (Examples of the rebate levels for APCs during this time frame are attached as Attachment A.)

Answer:

32. Amgen states that the best evidence of the contents of its APC contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 32 of the Complaint.

Complaint:

33. Later in 2004, Amgen modified its APCs. Amgen apparently recognized that simply providing an oncology clinic with a combined dollar volume target might give the clinic

the flexibility of loading up on Amgen's WBCGF drugs to meet its combined dollar volume target. As a result, Amgen imposed restrictions on the amount of WBCGF drugs that could be considered for purposes of reaching the specified dollar volume targets or higher rebate levels. This forced oncology clinics to purchase more Aranesp, which was not subject to any incentive restrictions to reach higher rebate levels.

Answer:

33. Amgen states that the best evidence of the contents of its APC contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 33 of the Complaint.

Complaint:

34. Amgen also required minimum dollar volume requirements for Aranesp. In addition, Amgen increased the rebates offered to oncology clinics, further penalizing those oncology clinics that failed to meet the dollar volume requirements set forth in each clinic's APC. With these changes to the APC, Amgen sought to more closely tie the rebates on its monopoly WBCGF drugs to the purchase of substantial amounts of Aranesp.

Answer:

34. Amgen states that the best evidence of the contents of its APC contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 34 of the Complaint.

Complaint:

35. Under the modification to the APCs in late 2004, a large oncology clinic that purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive an 18.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive a 30.0% rebate on its Aranesp purchases and a 25.0% rebate on its WBCGF drug purchases. (Examples of the rebate levels for APCs during this time frame are attached as Attachment B).

Answer:

35. Amgen states that the best evidence of the contents of its APC contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 35 of the Complaint.

Complaint:

36. All of these changes forced a clinic to buy less Procrit and more Aranesp in order for the clinic to get access to both the WBCGF and RBCGF rebates.

Answer:

36. Amgen denies that its discount programs forced any clinic to buy less Procrit® and more Aranesp®. Amgen states that the best evidence of the contents of its APC contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 36 of the Complaint.

Complaint:

37. As a result of these pricing schemes, Ortho's share of sales to oncology clinics has dropped precipitously. In the first quarter of 2004, Ortho had a 55% share of the oncology clinic market for RBCGF drugs and Amgen had a 45% share. At present, Ortho's share is estimated to be approximately 34%, with Aranesp having a 66% share.

Answer:

37. Amgen avers that any decline in Ortho's share of RBCGF drug sales to oncology clinics is the result of many factors, including the introduction of an alternative to Procrit, price competition, patient preference among treatment regimens, and physician choice. Amgen denies each and every remaining allegation contained in Paragraph 37 of the Complaint.

Complaint:

38. This significant shift in relative market share is attributable to oncology clinics being coerced by Amgen to replace substantial volumes of Procrit with Aranesp in order for these customers to gain access to acceptable pricing on the WBCGF drugs they must buy from Amgen.

Answer:

38. Amgen denies each and every allegation contained in Paragraph 38 of the Complaint.

Complaint:

39. The effect of Amgen's coercive tying arrangements on sales of RBCGF drugs to oncology clinics is evidenced by comparing Procrit and Aranesp market shares to oncology clinics with their respective share of sales in another market - sales to retail drug stores - where Amgen has not introduced these tying arrangements. As a result, Procrit and Aranesp compete head to head without interference from Amgen's WBCGF monopoly drugs. Procrit's share of sales to retail drug stores remains at approximately 70%.

Answer:

39. Amgen states that while retail drug stores are not a properly defined relevant market for RBCGF drugs, Amgen lacks information or knowledge sufficient to form a belief whether Procrit's® share of sales to retail drug stores is approximately 70%. Amgen denies each and every remaining allegation contained in Paragraph 39 of the Complaint.

Complaint:

40. Having gained a 65% share of sales to oncology clinics by tying access to WBCGF drug rebates to substantial purchases of Aranesp instead of Procrit, Amgen has now sought to tighten its squeeze on this market. Effective October 1, 2005, Amgen's pricing scheme became significantly more coercive.

Answer:

40. Amgen denies each and every allegation contained in Paragraph 40 of the Complaint.

Complaint:

41. As with the old pricing scheme, each clinic is given a series of levels of dollar volume targets for its total Amgen purchases of RBCGF and WBCGF drugs, as illustrated below for a large account.[1] The higher the Amgen gross purchases the higher level of rebate an oncology clinic can achieve:

	Rebates		
	Aranesp	Neulasta®	Neupogen
Level of Amgen Purchases			
6	26.0%	21.0%	20.0%
5	25.5%	20.5%	19.0%
4	25.0%	20.0%	18.0%
3	24.5%	19.5%	17.0%
2	24.0%	19.0%	16.0%
1	23.5%	18.5%	15.0%
base level	23.0%	18.0%	14.0%

Answer:

41. Amgen states that the best evidence of the contents of its APC contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 41 of the Complaint.

[1] Examples for medium and small accounts are set forth in Attachment C [Footnote found in complaint].

Complaint:

42. However, to gain access to even the lowest rebate level described above an oncology clinic must now meet separate Aranesp and Neulasta dollar volume triggers. To avoid being penalized on its purchases of Amgen's dominant WBCGF drugs, the dollar volume for Aranesp purchases that an oncology clinic must achieve is now based on up to 75% of the oncology clinic's total RBCGF product purchases being Aranesp, i.e., a 75% market share.

Answer:

42. Amgen states that the best evidence of the contents of its APC contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen further avers that clinics choosing not to enter into Amgen's discount program may continue to receive discounts from Amgen on Amgen's RBCGF and WBCGF drugs regardless of their level of purchases and whether they buy only one type of drug. Amgen denies each and every remaining allegation contained in Paragraph 42 of the Complaint.

Complaint:

43. A higher initial dollar volume threshold for Aranesp is only the start of this latest tying scheme. The true purpose of the new pricing scheme is to require oncology clinics to make Aranesp more than 75% of their RBCGF purchases. Under the modified APCs, for an oncology clinic to receive the same aggregate value it had been receiving while performing under the pre-October 1st APC (described above), each clinic now must reach higher dollar volume (i.e., market share) levels of Aranesp. For example, for a large clinic, the top Aranesp rebate is now 26%. This is 4% less than under the previous Amgen bundle of 30%. However, the clinic can earn back the additional 4% by taking its Aranesp share up to 90% as well as ensuring that Neulasta represents 90% of its WBCGF drug purchases. Thus, this new pricing scheme is intended to raise the Aranesp levels well above the initial threshold number needed to qualify for any rebate.

Answer:

43. Amgen states that the best evidence of the contents of its APC contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 43 of the Complaint.

Complaint:

44. The new pricing scheme also reduces the highest Neulasta rebate from 25% to 21% for large clinics. As with the Aranesp rebates, an oncology clinic can earn back the 4% on Neulasta if 90% of its WBCGF drug purchases are of Amgen's Neulasta and the higher threshold for Amgen's Aranesp (up to 90%) is met.

Answer:

44. Amgen states that the best evidence of the contents of its APC contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 44 of the Complaint.

Complaint:

45. The October 2005 addendum to the APC continues to place limits on the amount of the WBCGF drugs that may be considered for purposes of determining rebate levels on gross purchases. Conversely, the APC does not place caps on Aranesp. This further drives oncology clinics to purchase all or substantially all of their RBCGF drugs from Amgen.

Answer:

45. Amgen states that the best evidence of the contents of its APC contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 45 of the Complaint.

Complaint:

46. A clinic that does not meet its Aranesp volume requirement will only receive a 4% rebate on Neulasta. Previously, an oncology clinic that did not meet its Aranesp dollar volume target requirements in its APC nonetheless would receive a rebate of 7.1% to 9.5% on Neulasta. Thus, a non-conforming oncology clinic is now being penalized an additional 3.1 % to 5.5% on its Neulasta purchases.

Answer:

46. Amgen states that the best evidence of the contents of its APC contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 46 of the Complaint.

Complaint:

47. Failing to achieve a dollar volume of purchases of Aranesp roughly equivalent to a 75% market share will have severe economic consequences on an oncology clinic. Because the use of WBCGF drugs is the standard of care to treat neutropenia, oncology clinics have no choice but to carry Neulasta.

Answer:

47. Amgen admits that the use of WBCGF drugs is the standard of care to treat neutropenia. Amgen denies each and every remaining allegation contained in Paragraph 47 of the Complaint.

Complaint:

48. Medicare patients make up roughly 40% of the patient population treated in oncology clinics. As such, the economics of treating this patient group is a major consideration for any clinic. Without the Neulasta rebates (up to 25%), under the government's current reimbursement formula an oncology clinic would have to pay Amgen hundreds of dollars more on each treatment of Neulasta for a Medicare patient than the clinic will receive in reimbursement from the government and patients.

Answer:

48. Amgen admits that oncology clinics treat a number of Medicare patients, the exact proportion of which will depend on numerous factors and will vary among different clinics. Amgen denies each and every remaining allegation contained in Paragraph 48 of the Complaint.

Complaint:

49. On January 1, 2005, the federal government changed the formula by which doctors and clinics are reimbursed for the drugs they purchase and administer in their offices. The new formula is based on the drugs' average selling price ("ASP" as it is known in the industry) plus 6%. Thus, if a clinic bought a drug that had an ASP of $1,000, the clinic would be reimbursed $1,060. This reimbursement amount is static regardless of what the particular clinic actually paid for the drug. The "plus 6%" is not intended to be profit to an oncology clinic. It is to provide the clinic with some cover on costs associated with the acquisition and storage of the drug, other costs associated with purchasing expensive drugs that require refrigeration, and bad debt from patients who do not make co-pays.

Answer:

49. Amgen admits that on January 1, 2005 the federal government implemented a new method of reimbursement for certain drugs administered in a physician's office incident to other services provided in the office setting. Amgen further admits that under the 2005 Medicare reimbursement formula for physician administered drugs provided in the office setting, the amount of reimbursement is based on an Average Sales Price (ASP) that reflects the average sales price for that drug to most commercial providers and purchasers, including hospitals and retail outlets, plus 6%, and that reimbursement of specific claims does not take into account the cost of acquisition to a specific provider. Amgen avers that the Medicare reimbursement program has been subject to numerous changes in recent years, some of which will continue to be implemented, and may be further changed, in the future. In addition, the ASP calculation is subject to revision on a quarterly basis, so that reimbursement amounts can vary by quarter. Amgen states that it lacks sufficient knowledge or information to form a belief concerning the reasons for the "plus 6%" component and on that basis denies the allegation. Amgen denies the remaining allegations contained in Paragraph 49 of the Complaint.

Complaint:

50. As the term suggests, the ASP of a drug is an average based on the prices paid - and discounts and rebates earned - by all purchasers of such drugs. Accordingly, a Medicare

provider that does not, or can not, - avail itself of all of the rebates offered by a manufacturer can end up paying the manufacturer more for the drug than the drug's ASP and even more than the amount the provider will be reimbursed by the government (ASP + 6%). Where the price paid exceeds the reimbursement amount, the provider actually realizes a loss on the acquisition of a particular drug.

Answer:

50. Amgen admits that the ASP of a drug is an average based on the prices paid, and discounts and rebates earned, by most commercial purchasers of such drugs, but excluding other specified purchasers. Amgen admits that the cost of acquisition for any drug can, depending on the discounts and rebates obtained, exceed the amount by which Medicare reimburses that drug for Medicare patients. Amgen denies that whenever the price paid for a drug exceeds the Medicare reimbursement amount, the provider actually realizes a loss on the acquisition of a particular drug. There are a variety of factors, including without limitation wholesaler discounts, dosing regimens, the clinic's unique payor mix, and practice economics and efficiencies that can prevent the realization of a loss for a clinic even when the price paid for a particular administration of a drug exceeds the government reimbursement amount. Amgen denies each and every remaining allegation contained in Paragraph 50 of the Complaint.

Complaint:

51. Unless an oncology clinic qualifies for Amgen's rebates, this is precisely the situation the clinic will face when it administers Neulasta, Amgen's dominant WBCGF product, as the following example illustrates: Neulasta's list price is $2,603.00. The Medicare reimbursement (i.e., ASP plus 6%) per unit of Neulasta currently is $2,078.066 in 4th quarter 2005 as published by the Centers for Medicare and Medicaid Services ("CMS"). That amount is 20.17% or $524.93 below Neulasta's list price due to the rebates and incentives previously granted by Amgen. Thus, to break even on a per treatment basis, a clinic must receive rebates and discounts equal to 20.17% below Amgen's list price. Amgen currently provides oncology clinics with just a 5% discount off list price and a 4% rebate if the clinics fail to buy the requisite levels of Aranesp specified in their modified APCs. In other words, unless the clinics meet the Aranesp volume requirements, the clinic will pay Amgen $295.87 more per administration of Neulasta than the clinic is being reimbursed by the government.

Answer:

51. Amgen admits that the Medicare reimbursement (i.e., ASP plus 6%) per unit of Neulasta currently is $2,078.066 in the fourth quarter of 2005, but avers that the reimbursement is subject to adjustment in 2006. Amgen denies each and every allegation contained in Paragraph 51 of the Complaint.

Complaint:

52. The foregoing example is based on Neulasta's existing list price. Reportedly, Amgen is in the process of increasing the list price of Neulasta. A list price increase will result in an oncology clinic losing even more money.

Answer:

52. Amgen denies each and every allegation contained in Paragraph 52 of the Complaint.

Complaint:

53. Amgen's latest pricing scheme will force oncology clinics to attempt to meet Amgen's enhanced dollar volume requirements for Aranesp that translate into substantial market share requirements. This will create a strong incentive on the part of the oncology clinic to stock only Aranesp, or to reduce dramatically the level of Procrit stocked. Few oncology clinics will be able to bear the cost and financial risk of also stocking Procrit given the level of Amgen's dollar volume requirements for Aranesp. An oncology clinic which wanted to use even a small amount of Procrit would need to stock both Procrit and Aranesp but would have to carefully manage and monitor relative usage of Aranesp and Procrit, with severe financial consequences should it err in this process. Most are in no position to take such risks.

Answer:

53. Amgen denies each and every allegation contained in Paragraph 53 of the Complaint.

Complaint:

54. Amgen's current efforts to leverage its monopoly in the WBCGF drug market by penalizing oncology clinics that do not buy substantial amounts of Aranesp, coupled with the Medicare reimbursement regime preclude Ortho from competing over the long-term in the RBCGF oncology clinic market. Ortho understands that one Amgen official already has boasted to a Procrit customer that they expect 75% of existing Procrit customers will agree to Amgen's latest pricing scheme. Amgen already has nearly 65% of RBCGF drug sales in the oncology clinic market. The large scale conversion of existing Procrit accounts will effectively eliminate physician and consumer choice, as Procrit is driven out of the oncology clinic market.

Answer:

54. Amgen denies each and every allegation contained in Paragraph 54 of the Complaint.

Complaint:

55. Ortho is an equally efficient competitor, and Ortho supports price competition between rival companies as the hallmark of a free market. Ortho is prepared and willing to engage in fair, head-to-head, price competition between Procrit and Aranesp. But given the way in which government reimbursement works for a large percentage of a clinic's patients, Amgen's scheme of tying rebates on its monopoly drug to purchases of its RBCGF drug effectively precludes Ortho from responding with commensurate price cuts. That will only result in Ortho inevitably pricing below cost and in less competition.

Answer:

55. Amgen lacks information and knowledge sufficient to form a belief concerning the truth of the allegation that Ortho is an "equally efficient competitor" under applicable laws, and, on that basis, denies each such allegation. Amgen denies each and every remaining allegation contained in Paragraph 55 of the Complaint.

Complaint:

56. As alleged in paragraph 49, the government's reimbursement formula for Medicare patients for Procrit and Aranesp is based on each product's ASP plus 6%. Absent Amgen's tying arrangements in which WBCGF rebates are tied to Aranesp purchases, price

competition between Aranesp and Procrit (in the form of discounts or rebates) would result in Aranesp and Procrit each having a lower ASP as the government recalculates product ASPs. Here, the rebates provided on Neulasta, while tied by Amgen to an oncology clinic buying a certain volume of Aranesp, are not, and will not be, considered as the Aranesp ASP is recalculated by the government. As a result, offering Neulasta rebates tied to Aranesp purchases allows Amgen to make it financially attractive to buy Aranesp, but in a way which avoids the corresponding effect of a lower Aranesp ASP (which, in turn, provides an oncology clinic with a smaller cushion, in dollar terms, on reimbursement for Aranesp, i.e., 6% of a lower ASP).

Answer:

56. Amgen incorporates by reference its answer to Paragraph 49. Amgen denies each and every remaining allegation contained in Paragraph 56 of the Complaint.

Complaint:

57. Put simply, by tying together rebates on WBCGF drugs with purchases of Aranesp, Amgen is forcing Ortho to absorb on its one product the "discounts" Amgen has spread over two products. The result of Ortho having to absorb discounts on its one product, Procrit, is that it will drive the Procrit ASP down and correspondingly the level of government reimbursement on Procrit. Because, however, the WBCGF rebates are a disguised way of discounting Aranesp, the Aranesp ASP will not go down correspondingly.

Answer:

57. Amgen specifically denies that its APC program is anticompetitive, and avers that Ortho itself regularly offers bundled discounts across the broad basket of products offered by the Johnson & Johnson family of companies, including other drugs, implantable medical devices, and other essential hospital products. Ortho offers these discount bundles in the clinic, hospital, long term care, and other settings throughout the relevant market. Amgen denies each and every allegation contained in Paragraph 57 of the Complaint.

Complaint:

58. The lack of parity in the lowering of the ASPs of Procrit and Aranesp – because of the Amgen tie - puts Ortho at an enormous disadvantage and effectively precludes price competition. If Ortho offers a discount on Procrit commensurate with discounts offered by

Amgen on its WBCGF and RBCGF drugs, a lower ASP for Procrit will be recalculated by the government at subsequent reporting intervals. (ASPs are recalculated each quarter based on pricing data from two quarters earlier.) Procrit will then have to offer an additional discount on the lower ASP because an ASP plus 6% reimbursement on a lower ASP provides the clinic with less money to cover its costs (i.e., 6% of a lower ASP). While Ortho would be required to make up the difference in dollars to oncology clinics under a lower Procrit ASP, Amgen will not on Aranesp. Amgen's rebates are tied in large measure to its WBCGF drugs. Consequently, the Aranesp ASP will not drop to the same extent as Procrit's. The result of Procrit having a lower ASP than Aranesp will force Ortho to continue to chase Procrit's ASP down - each drop in the Procrit ASP will require an additional discount on the lower ASP to make up the dollar discount to oncology clinics to cover their costs. Meanwhile, the Aranesp ASP remains stable because Amgen's WBCGF rebates will not affect the Aranesp ASP, although they are tied to and driving Aranesp sales. The Procrit price spiral will result in Ortho pricing Procrit below cost in order to match the Amgen's rebates on its WBCGF and RBCGF drugs.

Answer:

58. Amgen admits that, as required by applicable regulations, Amgen calculates the ASP for each product separately, without regard to whether the purchase of one product entitled the purchaser to discounts or rebates on other drugs; Amgen is informed and believes that Ortho uses this same method to calculate the ASP for Procrit® and the other drugs that Ortho and other Johnson & Johnson companies offer to purchasers of Procrit®. Amgen denies each and every remaining allegation contained in Paragraph 58 of the Complaint.

Complaint:

59. It is anticipated that on January 1, 2006, the government will move hospital reimbursement for Medicare outpatients to an ASP reimbursement system. Hospitals reportedly will be reimbursed at ASP plus 8%. The adoption of an ASP reimbursement system in hospitals will allow Amgen to introduce into hospitals the same pricing scheme it is now using to foreclose competition in the sale of RBCGF drugs to oncology clinics. Amgen will again simply leverage its monopoly in WBCGF drugs to provide, in effect, rebates on Aranesp without impacting the Aranesp ASP.

Answer:

59. Amgen admits that it anticipates that on January 1, 2006, the government will revise the formula for reimbursing hospitals for drugs provided to Medicare beneficiaries in an

outpatient setting, and is informed and believes that the initial reimbursement rate for hospitals will be ASP plus 6%. Amgen denies that either the implementation of ASP in the hospital outpatient setting or the implementation of combined discounts by Amgen to hospitals would foreclose or hamper Ortho's ability to compete, especially because Johnson & Johnson offers bundled discounts to hospitals throughout the United States. Amgen denies each and every remaining allegation contained in Paragraph 59 of the Complaint.

Complaint:

60. Procrit was the subject of extensive clinical trials demonstrating its effectiveness in the treatment of anemia and millions of Americans have been administered Procrit over the past 14 years. Recent studies and reports continue to underscore Procrit's efficacy.

Answer:

60. Amgen admits that Procrit® was the subject of clinical trials evaluating its effectiveness in the treatment of anemia and that there is a recent study reporting Procrit's® efficacy, and refers to the unspecified studies and reports as the best evidence of their content. Amgen lacks information or knowledge sufficient to form a belief concerning the number of patients who have been administered Procrit®. Amgen denies the remaining allegations of Paragraph 60 of the Complaint.

Complaint:

61. In May 2005, the results of a comparative clinical trial involving Aranesp and Procrit designed specifically to measure the rate of hemoglobin improvement were presented at the annual meeting of the American Society of Clinical Oncology ("ASCO"). The study authors, led by Dr. Roger Waltzman of Saint Vincent's Comprehensive Cancer Center, concluded (1) a trend toward a lower rate of transfusion in Procrit-treated patients when compared to Aranesp-treated patients, and (2) a significant difference between treatments in the total number of red blood cell units transfused, with Procrit-treated patients requiring far fewer units per patient transfused than Aranesp treated patients.

Answer:

61. Amgen admits that in May 2005, the results of a comparative clinical trial involving Aranesp® and Procrit® by Dr. Roger Waltzman were presented at the annual meeting of the American Society of Clinical Oncology ("ASCO"). Amgen avers that the study has design flaws making its difficult to interpret its findings and refers to the results of that trial and the presentation as the best evidence of their content. Amgen denies each and every remaining allegation contained in Paragraph 61 of the Complaint.

Complaint:

62. Aside from the expense, time and invasive nature of the procedure, transfusions present numerous medical risks. Chemotherapy patients are significantly benefited by a reduction in the number of transfusions and the amount of blood transfused, as is the health care system as a whole since the available blood supply for emergency use in other patients is not otherwise depleted.

Answer:

62. Amgen admits that transfusions present risks, and that a reduction in the number of transfusions for chemotherapy patients is beneficial for a variety of reasons. Amgen lacks information or knowledge sufficient to form a belief concerning the truth of the remaining matters stated in Paragraph 62, and on that basis denies such statements.

Complaint:

63. Also, in May 2005 at the ASCO meeting, there was a presentation on a comparative study of Procrit and Aranesp sponsored by Amgen and led by Dr. John Glaspy of the University of California at Los Angeles. The study was designed to find "non-inferiority" of either product if the level of transfusions fell within a broad range. Having defined equivalence in these broad terms, the study concluded that Procrit and Aranesp were not inferior to one another.

Answer:

63. Amgen admits that in May 2005 at the ASCO meeting, there was a presentation on a comparative study of Procrit® and Aranesp® led by Dr. John Glaspy, and refers to that study and the presentation as the best evidence of their contents. Amgen denies that the study was designed to find "non-inferiority" of either product if the level of transfusions fell within a broad range. Amgen denies each and every remaining allegation contained in Paragraph 63 of the Complaint.

Complaint:

64. Finally, at the May 2005 meeting, there was a presentation based on an independent, retrospective chart review conducted by Dr. A.S. Case with the University of Alabama at Birmingham. The review was directed at determining the transfusion rates after treatment with Procrit and Aranesp. Based on this observational data, the authors found that a significantly lower proportion of patients required transfusions, and fewer total units were transfused, when treated with Procrit rather than Aranesp.

Answer:

64. Amgen admits that at the May 2005 ASCO meeting, there was a presentation based on a chart review by Dr. A.S. Case with the University of Alabama at Birmingham, and refers to that study and presentation as the best evidence of their contents. Amgen avers that randomized controlled trials concerning various cancer cohorts have found no significant difference in transfusion rates between Procrit® and Aranesp® patients. Amgen denies each and every remaining allegation contained in Paragraph 64 of the Complaint.

Complaint:

65. Amgen's pricing schemes have caused and will continue to cause anti-competitive effects in the relevant product markets. Amgen economically coerces oncology clinics to purchase its RBCGF product, Aranesp, as a condition for receiving substantial price rebates on products that they must purchase from Amgen – WBCGF drugs. Unless they purchase significant amounts of their RBCGF drugs from Amgen, oncology clinics will not qualify for the

massive rebates provided on Amgen's dominant WBCGF drugs. Moreover, if they agree to buy virtually all of their RBCGF and WBCGF drugs from Amgen, oncology clinics are given even higher rebates. The only economically viable option for these oncology clinics is to purchase all or nearly all of their RBCGF drugs from Amgen, even though many physicians would prefer Procrit if Aranesp competed head-to-head with Procrit.

Answer:

65. Amgen denies each and every allegation contained in Paragraph 65 of the Complaint.

Complaint:

66. Amgen's actions substantially foreclose Ortho from selling Procrit to oncology clinics. This foreclosure is demonstrated by the significant market share shift that has occurred and will continue to occur as Amgen ratchets up its leverage by implementing its latest pricing scheme.

Answer:

66. Amgen denies each and every allegation contained in Paragraph 66 of the Complaint.

Complaint:

67. This anticompetitive foreclosure has caused Ortho to lose revenue and profits that it otherwise would have earned, disrupted Ortho's relationships with Oncology clinics, resulted in loss of good will and other harm to Ortho's ability to innovate and compete.

Answer:

67. Amgen denies each and every allegation contained in Paragraph 67 of the Complaint.

Complaint:

68. The anti-competitive effects of Amgen's tying and attempts to monopolize extend far beyond the substantial foreclosure of Ortho, which is Amgen's only competitor in the sale of RBCGF drugs. There are numerous other potential uses for epoetin alfa that will likely develop in free and competitive drug markets. Without achieving a reasonable rate of return on current uses of Procrit, the ability of Ortho to fund current and future research and development projects related to alternative uses of Procrit and to seek regulatory approvals for these alternative uses is substantially reduced. Ortho's ability to enter new markets with Procrit, either as a first mover or as a challenger to incumbents, is severely undermined by Amgen's tying and attempt to monopolize.

Answer:

68. Amgen admits that currently Ortho is Amgen's only competitor in the sale of RBCGF drugs. Upon information and belief, other companies are developing RBCGF drugs and products to compete with RBCGF drugs. Amgen admits that there are numerous other potential uses for Epoetin alfa that likely will develop in free and competitive drug markets, and avers that entry of Aranesp® into the market has enhanced competition and innovation. Amgen denies each and every remaining allegation contained in Paragraph 68 of the Complaint.

Complaint:

69. Amgen's tying arrangement would also require potential RBCGF drug competitors to price their product below any true measure of cost in the pharmaceutical industry, even if these potential competitors were as efficient as Amgen. In this manner, Amgen's tying arrangement has caused and will cause anticompetitive effects by increasing the barriers to entry into RBCGF drug markets.

Answer:

69. Amgen denies each and every allegation contained in Paragraph 69 of the Complaint.

Complaint:

70. In addition, Amgen's conduct enhances and reinforces its monopoly power in the market for WBCGF drugs.

Answer:

70. Amgen denies each and every allegation contained in Paragraph 70 of the Complaint.

Complaint:

71. Amgen's latest pricing scheme is intended to foreclose Ortho from a sizeable segment of the oncology clinic market, and will embolden Amgen to take similar action in the hospital market. This development will have a devastating impact on Ortho and on patient care. Ortho will lose important longstanding customer relationships as well as the goodwill built up over the years of the Procrit franchise which has been used to treat millions of cancer patients suffering from the severe anemia that often accompanies chemotherapy. Amgen's actions will likely result in reductions in investments in ongoing research and development in order to provide better forms of treatment.

Answer:

71. Amgen denies each and every allegation contained in Paragraph 71 of the Complaint.

Complaint:

72. Eliminating Ortho as an effective competitor in the oncology clinic market will also result in less physician choice. Physicians and patients should not be effectively cut off from access to the benefits of Procrit-which many physicians would prefer to Aranesp by virtue of Amgen's use of its monopoly leverage in the sale of WBCGF drugs.

Answer:

72. Amgen admits that physicians and patients should be able to choose a drug based on clinical benefits and other important factors, and avers that entry of Aranesp® into the

product market enhances physician, patient, and payor choice. Amgen denies each and every remaining allegation contained in Paragraph 72 of the Complaint.

Complaint:

73. If Amgen is permitted to implement its latest pricing scheme into the oncology clinic market, with the success that is envisioned and is economically predictable, Amgen will simply do the same thing in the hospital market when hospitals are reimbursed under an ASP system in January of 2006. This will compound the irreparable harm to Ortho and physicians and patients.

Answer:

73. Amgen denies each and every allegation contained in Paragraph 73 of the Complaint.

Complaint:

74. There is no legitimate business purpose or efficiency justification for Amgen's pricing schemes. Amgen has employed these schemes for the sole purpose of eliminating Ortho and potential entrants as competitors in the sale of RBCGF drugs to oncology clinics.

Answer:

74. Amgen denies each and every allegation contained in Paragraph 74 of the Complaint.

Complaint:

75. RBCGF drugs are sold through various channels. The roughly 2,400 oncology clinics in the United States represent the largest market for Procrit and Aranesp, with over $2.8 billion in gross sales projected in 2005. "Oncology clinics" include the small number of "mixed use" clinics that provide oncology as well as other clinic services.

Answer:

75. Amgen admits that RBCGF drugs are sold to various types of providers and purchasers, many of which provide RBCGF drug treatment to cancer patients, and that it projects over $2.8 billion in gross sales of RBCGF drugs to oncology clinics in 2005. Amgen denies that oncology clinics are a properly defined relevant market. Amgen denies each and every remaining allegation contained in Paragraph 75.

Complaint:

76. To be successful, a seller of RBCGF drugs must have a strong presence in oncology clinics. These clinics, which are often owned and operated by oncologists in private practice, are the preferred venue for patients to receive out-patient administration of RBCGF drugs as well as WBCGF drugs. At present, the vast majority of outpatient administration of RBCGF drugs occurs in oncology clinics.

Answer:

76. Amgen admits that both Ortho and Amgen, as sellers of RBCGF drugs, vigorously compete for sales of RBCGF drugs to all providers of RBCGF drugs (except to providers treating anemia associated with ESRD). Amgen denies that the vast majority of outpatient administration of RBCGF drugs occurs in oncology clinics. Amgen lacks information and knowledge sufficient to form a belief as to the truth of the remaining allegations and, on that basis, denies each and every remaining allegation contained in Paragraph 76 of the Complaint.

Complaint:

77. Both Amgen and Ortho have historically treated oncology clinics as a distinct market. Amgen and Ortho participate in audits of epoetin alfa sales designed to align dialysis (Epogen) and non-dialysis Procrit sales in accordance with the license. The audit methodology was formulated by Amgen. It treats oncology clinics as a distinct market segment because oncology clinics use RBCGF drugs exclusively to treat anemia associated with non-dialysis indications. Because the non-dialysis indications belong to Ortho under the PLA, the audit treats all sales to oncology clinics of both parties' brands of epoetin alfa (Epogen or Procrit) as belonging to Ortho.

Answer:

77. Amgen avers that as part of a previous arbitration Ortho and Amgen implemented an audit methodology, avers that the audit methodology was accepted by an arbitrator, and denies that the existence or terms of the audit methodology evidence a market for antitrust purposes. Amgen admits that the audit deems all sales of Epogen® or Procrit® to oncology clinics as belonging to Ortho. Amgen denies each and every remaining allegation contained in Paragraph 77 of the Complaint.

Complaint:

78. Amgen and Ortho have also recognized oncology clinics as a distinct market in their pricing. The pricing scheme that is the subject of Ortho's Complaint is being offered only to oncology clinics, and Amgen has used this distinction in other pricing programs. For instance, in the past, Amgen offered hospitals 30% "off invoice" discounts for the purchase of Aranesp, but did not offer oncology clinics this favored "off invoice" pricing.

Answer:

78. Amgen states that the best evidence of the contents of its contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 78 of the Complaint.

Complaint:

79. An analysis of prices for Procrit shows that oncology clinics on average pay roughly 5% more for the drug than do hospitals.

Answer:

79. Amgen lacks information and knowledge sufficient to form a belief as to the truth of the allegation that an analysis of prices for Procrit® shows that oncology clinics on average

pay roughly 5% more for the drug than do hospitals and, on that basis, denies each and every allegation in Paragraph 79 of the Complaint.

Complaint:

80. Hospitals cannot buy more RBCGF drugs than they need and "arbitrage" a portion of their purchases by reselling to oncology clinics. It has been a longstanding practice in the pharmaceutical business to have "own use" clauses in sales contracts precluding resale for profit.

Answer:

80. Amgen states that the best evidence of the contents of the alleged sales contracts is the contracts themselves, and refers to the contracts for the terms thereof. Amgen denies each and every remaining allegation contained in Paragraph 80 of the Complaint.

Complaint:

81. Government health care programs, such as Medicare, also treat oncology clinics differently than other purchasers. The amount of reimbursement and the formula utilized by the government are different than what are used for other industry participants, such as hospitals.

Answer:

81. Amgen admits that reimbursement under governmental health care programs, including Medicare, will depend on a variety of factors, including coverage of a particular diagnosis, place of service, and type of provider. Amgen admits that under these governmental regulations the reimbursement received by a hospital for administration of a drug in a typical hospital outpatient clinic can be different than the reimbursement provided to a privately owned oncology clinic, just as it will be different from the reimbursement provided by that same hospital in the inpatient setting, and it will be different from the reimbursement provided to

certain other hospitals. Amgen denies each and every remaining allegation contained in Paragraph 81 of the Complaint.

Complaint:

82. Most oncology clinics purchase drugs through entities called "specialty distributors." Specialty distributors deliver oncology drugs, which often require careful handling (e.g., refrigeration), to thousands of oncology clinics. These specialty distributors are licensed to distribute to oncology clinics.

Answer:

82. Amgen, upon knowledge, information and belief, admits that as a matter of preference, many oncology clinics purchase certain drugs through "specialty distributors." Amgen admits that some oncology drugs like many drugs, require careful handling, and that certain specialty distributors are licensed to distribute to oncology clinics, but lacks knowledge or information sufficient to form a belief about each and every remaining allegation of Paragraph 82 of the Complaint.

Complaint:

83. Oncology clinics have formed their own Group Purchasing Organizations ("GPO") to negotiate with drug manufacturers. Historically, certain purchasers of pharmaceuticals have benefited from collectively bargaining with drug manufacturers through GPOs. Hospitals, for instance, belong to GPOs. These hospital GPOs generally do not permit oncology clinics to participate. In recent years, oncology clinics began to form specialized GPOs in an effort to achieve lower prices.

Answer:

83. Amgen admits that many clinics and hospitals have formed or belong to GPOs and that those GPOs negotiate with drug manufacturers. Amgen lacks information and knowledge sufficient to form a belief as to the truth of the allegation that certain purchasers of

pharmaceuticals have benefited from collectively bargaining with drug manufacturers through GPOs and, on that basis, denies each such allegation. Amgen lacks information and knowledge sufficient to form a belief as to the truth of the allegation that hospital GPOs generally do not permit oncology clinics to participate and, on that basis, denies each such allegation. Amgen denies each and every remaining allegation contained in Paragraph 83 of the Complaint.

Complaint:

84. The sale of RBCGF drugs to oncology clinics is a market recognized by industry and government.

Answer:

84. Amgen denies each and every allegation contained in Paragraph 84 of the Complaint.

Complaint:

85. There are high barriers to entry in the sale of RBCGF drugs. Foremost are Amgen's exclusive patent rights over epoetin alfa. A market entrant would have to commit massive resources to fund clinical research to (l) demonstrate the safety and effectiveness of a new drug, and (2) secure regulatory approval for its distribution in the United States and (3) promote and sell the product, and (4) design around Amgen's formidable patent estate.

Answer:

85. Amgen admits that any entrant into the sale of RBCGF drugs must (l) demonstrate the safety and effectiveness of a new drug, and (2) secure regulatory approval for its distribution in the United States and (3) promote and sell the product, and (4) must not infringe applicable patents. Amgen denies each and every remaining allegation contained in Paragraph 85 of the Complaint.

Complaint:

86. The sale of WBCGF drugs in the United States is a relevant product market separate and distinct from the sale of RBCGF drugs.

Answer:

86. Amgen admits that sales of WBCGF drugs are separate and distinct from sales of RBCGF drugs, which are sold to different types of customers such as oncology clinics, hospitals, etc. Amgen denies each and every remaining allegation in Paragraph 86 of the Complaint.

Complaint:

87. WBCGF drugs are unique products, as they are the only products that alleviate the symptoms associated with treatment-induced neutropenia.

Answer:

87. Amgen admits that WBCGF drugs are the standard of care for alleviating the symptoms associated with treatment-induced neutropenia. Amgen denies each and every remaining allegation contained in Paragraph 87 of the Complaint.

Complaint:

88. Recognizing this, the Federal Trade Commission ("FTC") stated that "the research, development, manufacture and sale of Neutrophil Regeneration Products" (a.k.a. WBCGF drugs) is a "relevant line of commerce" in a Clayton Act §7 administrative Complaint filed against Amgen and the Immunex Corporation.

Answer:

88. Amgen admits that the FTC's proposed administrative Complaint, which was placed in the public record as part of the Consent Order in Amgen's acquisition of the Immunex

Corporation, alleged that one line of commerce was "the research, development, manufacture and sale of Neutrophil Regeneration Products." Amgen denies each and every remaining allegation contained in Paragraph 88 of the Complaint.

Complaint:

89. The sale of WBCGF drugs to oncology clinics is a market recognized by industry and government.

Answer:

89. Amgen denies each and every allegation contained in Paragraph 89 of the Complaint.

Complaint:

90. There are high barriers to entry in the sale of WBCGF drugs. There are no potential entrants on the horizon. Any potential competitor to Amgen's WBCGF drug monopoly would face what Amgen claims is a broad patent portfolio. Therefore, to enter these markets, an entrant would have to commit massive resources to fund clinical research to (1) demonstrate the safety and effectiveness of a new drug, (2) and secure regulatory approval for its distribution in the United States and (3) promote and sell the product, and (4) design around Amgen's formidable patent estate.

Answer:

90. Amgen admits that a market entrant must (l) demonstrate the safety and effectiveness of a new drug, (2) secure regulatory approval for its distribution in the United States, (3) promote and sell the product, and (4) must not infringe applicable patents. Amgen denies each and every remaining allegation contained in Paragraph 90 of the Complaint.

CAUSES OF ACTION

FIRST CLAIM FOR RELIEF

(Per Se and Rule of Reason Unlawful Tying)

Complaint:

91. Ortho repeats and realleges each and every allegation contained in paragraphs 1 through 90 with the same force and effect as if here set forth in full.

Answer:

91. Amgen incorporates its answers in Paragraphs 1 through 90 as if set forth in full herein.

Complaint:

92. Amgen has engaged in an unlawful contract, combination, conspiracy and agreement in unreasonable restraint of trade and commerce, in violation of Section 1 of the Sherman Act, 15 U.S.C. §l. This includes agreements with oncology clinics that force them to purchase all or nearly all of their demand for RBCGF drugs from Amgen.

Answer:

92. Amgen denies each and every allegation contained in Paragraph 92 of the Complaint.

Complaint:

93. The product characteristics, uses and character of demand for RBCGF drugs -- which are used to treat chemotherapy-induced anemia but not neutropenia -- are different from the product characteristics, uses and the character of demand for WBCGF drugs -- products that treat neutropenia, but not anemia. RBCGF and WBCGF drugs are distinct products: they are used to treat different conditions and are not functionally interchangeable.

Answer:

93. Amgen admits the allegations contained in Paragraph 93 of the Complaint.

Complaint:

94. At all times relevant to this action, Amgen has had market power in the sale of WBCGF drugs sufficient to force oncology clinics that purchase WBCGF drugs to also purchase Aranesp regardless of whether these purchasers actually preferred Procrit.

Answer:

94. Amgen denies each and every allegation contained in Paragraph 94 of the Complaint.

Complaint:

95. A substantial amount of interstate commerce has been and is being affected by Amgen's tying arrangement. The total purchases of RBCGF drugs by oncology clinics in 2005 is projected to exceed $2.8 billion in gross sales.

Answer:

95. Amgen admits that the total purchases of RBCGF drugs by oncology clinics in 2005 are projected to exceed $2.8 billion in gross sales. Amgen denies each and every remaining allegation contained in Paragraph 95 of the Complaint.

Complaint:

96. Amgen's tying arrangement forces oncology clinics to purchase all or nearly all of their demand for RBCGF drugs from Amgen in a tied package with Amgen's WBCGF drugs. Pursuant to Amgen's pricing schemes, which offer significant rebates for the purchase of Amgen's dominant WBCGF drugs if they are purchased in a package with large quantities of Aranesp, the only economically viable option for oncology clinics that need WBCGF drugs is increasingly for them to purchase all or nearly all of their RBCGF drugs from Amgen.

Answer:

96. Amgen denies each and every allegation contained in Paragraph 96 of the Complaint.

Complaint:

97. Amgen's tying arrangement has substantially foreclosed and will continue to substantially foreclose Ortho from competing with Amgen for the sale of RBCGF drugs to oncology clinics based on the efficacy of its product and the price of its product on a stand-alone basis. Amgen's pricing scheme has reduced and will continue to reduce the ability and incentive for Ortho to work toward new applications for Procrit for patients who suffer from ailments or diseases not currently treated by Epoetin Alfa.

Answer:

97. Amgen denies each and every allegation contained in Paragraph 97 of the Complaint.

Complaint:

98. Amgen's tying arrangement has no legitimate business purpose. It achieves no legitimate efficiency benefits and has the anticompetitive effect of foreclosing competition on the merits for the sale of RBCGF drugs to oncology clinics.

Answer:

98. Amgen denies each and every allegation contained in Paragraph 98 of the Complaint.

Complaint:

99. Amgen's tying arrangement has adversely affected competition in the sale of RBCGF drugs to oncology clinics and will continue to do so unless enjoined.

Answer:

99. Amgen denies each and every allegation contained in Paragraph 99 of the Complaint.

Complaint:

100. As a result of Amgen's violations of Section 1 of the Sherman Act, Ortho has been injured in its business and property in an amount not presently known, but which is, at a minimum, in excess of one millions dollars, prior to trebling.

Answer:

100. Amgen denies each and every allegation contained in Paragraph 100 of the Complaint.

Complaint:

101. Such violation and the effects thereof are continuing and will continue unless injunctive relief is granted. Ortho has no adequate remedy at law.

Answer:

101. Amgen denies each and every allegation contained in Paragraph 101 of the Complaint.

SECOND CLAIM FOR RELIEF

(Attempt to Monopolize RBCGF Drug Market)

Complaint:

102. Ortho repeats and realleges each and every allegation contained in paragraphs 1 through 100 with the same force and effect as if here set forth in full.

Answer:

102. Amgen incorporates its answers in Paragraphs 1 through 101 as if set forth in full herein.

Complaint:

103. In violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, Amgen has willingly, knowingly, intentionally and with specific intent to do so, attempted to monopolize sales of RBCGF drugs to oncology clinics.

Answer:

103. Amgen denies each and every allegation contained in Paragraph 103 of the Complaint.

Complaint:

104. This attempt to monopolize has been effectuated by a variety of unlawful conduct undertaken with the purpose and effect of eliminating competition in the sale of RBCGF drugs, including but not limited to:

- conditioning the sale of RBCGF drugs on the purchase of WBCGF drugs;
- granting rebates on the sale of WBCGF drugs conditioned upon the purchase of RBCGF drugs from defendant;
- granting multi-product rebates conditioned upon meeting disguised market share requirements for RBCGF and WBCGF drugs; and
- entering into agreements that have the purpose and effect of requiring customers to purchase all or almost all of their requirements for RBCGF drugs from defendant.

Answer:

104. Amgen denies each and every allegation contained in Paragraph 104 of the Complaint.

Complaint:

105. There is a dangerous probability that Amgen, by using these exclusionary practices, will monopolize the sale of RBCGF drugs to oncology clinics.

Answer:

105. Amgen denies each and every allegation contained in Paragraph 105 of the Complaint.

Complaint:

106. Amgen's exclusionary practices have caused and will continue to cause substantial anticompetitive effects on the sale of RBCGF drugs to oncology clinics. Amgen's conduct has substantially foreclosed and will continue to substantially foreclose competition on the merits from Ortho in the sale of RBCGF drugs to oncology clinics and other customers. Amgen's conduct will also raise barriers to entry for potential competitors for the sale of RBCGF and WBCGF drugs. Amgen's conduct has also reduced and will continue to reduce the ability and incentive for Ortho to work toward new applications for Procrit to benefit patients who suffer from ailments or diseases not currently treated with Epoetin Alfa.

Answer:

106. Amgen denies each and every allegation contained in Paragraph 106 of the Complaint.

Complaint:

107. Amgen intends to take further acts aimed specifically at further foreclosing competition in the sale of RBCGF drugs to oncology clinics.

Answer:

107. Amgen denies each and every allegation contained in Paragraph 107 of the Complaint.

Complaint:

108. There is no legitimate business justification or pro-competitive benefit from Amgen's exclusionary practices.

Answer:

108. Amgen denies each and every allegation contained in Paragraph 108 of the Complaint.

Complaint:

109. As a result of Amgen' s violations of Section 2, Ortho has been injured in its business and property in an amount not presently known but which is, at a minimum, in excess of one millions dollars prior to trebling.

Answer:

109. Amgen denies each and every allegation contained in Paragraph 109 of the Complaint.

Complaint:

110. Such violation and the effects thereof are continuing and will continue unless injunctive relief is granted. Ortho has no adequate remedy at law.

Answer:

110. Amgen denies each and every allegation contained in Paragraph 110 of the Complaint.

Amgen denies that Ortho is entitled to any relief.

All allegations not specifically admitted are hereby denied.

AFFIRMATIVE DEFENSES

Amgen asserts the following affirmative defenses without assuming the burden of proof of any such defense that would otherwise rest with Ortho:

1. The Complaint fails to state a claim on which relief may be granted.

2. To the extent that Amgen engaged in any of the conduct alleged in the Complaint, its conduct was reasonable, justified, excused, privileged and/or in pursuit of lawful and legitimate business interests.

3. The Complaint is barred on the ground that the alleged conduct was, either in whole or in part, procompetitive in nature, and will promote, encourage, and increase competition. Accordingly, Amgen's conduct was reasonable, justified, and privileged.

4. The injuries and damages alleged by Ortho do not constitute legally cognizable antitrust injuries.

5. The damages allegedly suffered by Ortho were not caused in fact by any conduct or act of Amgen.

6. The damages allegedly suffered by Ortho were not proximately caused by any conduct or act of Amgen.

7. To the extent Ortho seeks damages for injury that occurred prior to the applicable limitations period, the Complaint is barred by the statute of limitations.

8. The Complaint is barred by the doctrine of laches.

9. The Complaint is barred by the doctrine of waiver.

10. The Complaint is barred by the doctrine of estoppel.

11. Ortho has failed to exercise reasonable care and diligence to mitigate its alleged injuries and damages, if any.

12. Any loss or damage allegedly suffered by Ortho was proximately caused by Ortho's decisions and business judgments in connection with the matters alleged in the Complaint and not by Amgen's alleged conduct or actions.

13. Ortho's alleged damages, if any, are speculative and impossible to ascertain.

14. Ortho has not sustained any irreparable harm or injury, and therefore is not entitled to any injunctive relief.

15. Amgen Inc. is not a proper party to this action.

16. Amgen hereby gives notice that it intends to rely upon any other defense that may become available or appear during discovery proceedings in this case and hereby reserves the right to amend this Answer to assert any such defense.

Respectfully submitted,

GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE, P.C.

By: /s/ Michael R. Griffinger
Michael R. Griffinger

- and-

Bobby R. Burchfield
Raymond A. Jacobsen, Jr.
Melvin White
MCDERMOTT WILL & EMERY LLP
600 Thirteenth Street
Washington, D.C.20005-3096
(202) 756-8000

David S. Rosenbloom
MCDERMOTT WILL & EMERY LLP
227 West Monroe Street
Chicago, Illinois 60606-5096
(312) 984-2000

Attorneys for Defendants Amgen Inc. and Amgen USA Inc.

Dated: November 15, 2005

Of Counsel:

Anna Richo
Mary Beth Campbell
C. Moze Cowper
AMGEN INC.
Once Amgen Center Drive
Thousand Oaks, CA 91320-1799
(805) 447-1000

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, it is hereby stated that the matter in controversy as against Defendants Amgen Inc. and Amgen USA Inc. is not the subject of any other action pending in any other Court or a pending arbitration proceeding to the best of my knowledge and belief.

GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE, P.C.

By: /s/ Michael R. Griffinger
Michael R. Griffinger

- and-

Bobby R. Burchfield
Raymond A. Jacobsen, Jr.
Melvin White
MCDERMOTT WILL & EMERY LLP
600 Thirteenth Street
Washington, D.C.20005-3096
(202) 756-8000

David S. Rosenbloom
MCDERMOTT WILL & EMERY LLP
227 West Monroe Street
Chicago, Illinois 60606-5096
(312) 984-2000

Attorneys for Defendants Amgen Inc. and Amgen USA Inc.

Dated: November 15, 2005

Of Counsel:

Anna Richo
Mary Beth Campbell
C. Moze Cowper
AMGEN INC.
Once Amgen Center Drive
Thousand Oaks, CA 91320-1799
(805) 447-1000